FEB 1 3 2003

K023012

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR OF THIS 510(K):	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive P.O. Box 988 Warsaw, Indiana 46581-0988
MANUFACTURER:	DePuy International Ltd Trading as DePuy CMW Cornford Road Blackpool, Lancashire FY 4 4QQ, England
510(K) CONTACT:	Janet Johnson, RAC DePuy Orthopaedics, Inc. Group Leader, Regulatory Submissions (574) 371-4907; FAX (574) 371-4987 E-mail: jjohnso7@dpyus.jnj.com
TRADE NAME:	SmartSet HV Bone Cement
COMMON NAME:	PMMA Bone Cement
CLASSIFICATION:	PMMA Bone Cement: Class II per 21 CFR 888.3027
DEVICE CODE:	LOD
EQUIVALENT DEVICES:	DePuy 1 Bone Cement – P960001/Supplement 3 Palacos R40 Bone Cement - P810020/Supplement 3

DEVICE DESCRIPTION AND INTENDED USE:
SmartSet HV Bone Cement is a high viscosity bone cement which is equally suited for both digital and syringe use. It has a short dough time (approximately 1 minute), a setting time of 9 - 11 mins and consequently a long working time. These handling characteristics make SmartSet HV Bone Cement ideally suited for use with modern cementing techniques and clinical applications. The subject device is for single use only and is available in either 20g or 40g single unit packs and 10 ×1 unit dispenser cartons. Each single unit (device) pack consists of a polymeric powder component and a monomeric liquid component.

SmartSet HV Bone Cement is indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.

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BASIS OF SUBSTANTIAL EQUIVALENCE:

SmartSet HV Bone Cement has similar indications for use as other bone cements currently marketed in the United States. These predicate devices include:

1) DePuy 1 Bone Cement
2) Palacos R40 Bone Cement

All three bone cements are intended to be used for the fixation of artificial joints and prosthesis to host bone.

Based on similarities of design, materials, intended use, and testing performed, DePuy believes that the subject SmartSet HV Bone Cement is substantially equivalent to the above described FDA cleared devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2003

Ms. Janet G. Johnson, RAC
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K023012
Trade Name: SmartSet HV Bone Cement
Regulation Number: 21 CRF 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD
Dated: January 3, 2003
Received: January 6, 2003

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number (if known)

Device Name: SmartSet HV Bone Cement

Indications for Use:

SmartSet HV Bone Cement is indicated for the fixation of prostheses to living bone in orthopaedic musculoskeletal surgical procedures for rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.

Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhern

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number K023012

Prescription Use____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)